D002

## AMENDMENTS TO THE SPECIFICATION

## Objections to the specification

At page 2, please replace the paragraph beginning at line 23 and ending at line 26 with the following paragraph:

Yet, it has also unespectedly unexpectedly been found that, just in some body districts and organs, sulfatases exist which, under particular physiological conditions and situations, are able to convert again T<sub>2</sub>S into its active form T<sub>3</sub> (Ref's.7-9).

At page 3, please replace the paragraph beginning at line 17 and ending on page 4, line 6 with the following paragraph:

Further studies have been performed to ascertain the effective role played by T<sub>3</sub>S during production and metabolism of thyroid hormones. Said studies have recently demonstrated that it shows thyromimetic effects in hypothyroid rats (Ref. 10) as well as in euthyroid rats (Ref. 14). In both cases T<sub>3</sub>S has shown a potency of around one fifth that of T<sub>3</sub>. Moreover both treatments with T<sub>3</sub>S and with T<sub>3</sub> produced a significant reduction of serum levels of thyreotropic hormone (TSH) in euthyroid rats, thus showing to possess similar capability in inhibiting its secretion. On the contrary, in the case of hypothyroid rats, T<sub>3</sub>S showed a poor capability of inhibiting TSH secretion when compared to T<sub>3</sub>. It is well known that TSH is a highly responsive indicator to the functional status of thyroid gland and consents to detect the smallest alterations of its hormonal secretion. Actually, its levels are higher under conditions of reduced thyroid functionality, even in those conditions that are defined as sub-clinical, while they are reduced when an excess of thyroid hormones are present. Accordingly, T<sub>3</sub>S seems unespectedly unexpectedly non-comparable to T<sub>3</sub> as far as its capability of inhibition on formation of TSH is involved.

At page 4, please replace the paragraph beginning at line 19 and ending at line 21 with the following paragraph:

As a result, today the skilled technician is still facing a complex, somewhat conflicting, situation, which highlits highlights only some of the biological characteristics of the product and needs more exhaustive in depth studies.

At page 5, please replace the paragraphs beginning at line 15 and ending at line 20, and beginning at line 23 and ending at line 27 with the following paragraph:

It has now unespectedly unexpectedly been found, and this is one of the aspects of the present invention, that  $T_3S$ , as such or in association with other thyroid hormones or prohormones, preferably  $T_4$ , and properly formulated according to the desired application, is particularly useful as a medicament to be used in all those pathologies caused by insufficient production by the body of the needed quantities of active thyroid hormones, in particular  $T_3$ .

In fact, it has unespectedly unexpectedly been found that the administration of T<sub>3</sub>S, contrary to what known about its normal metabolism, allows to maintain steady levels of T<sub>3</sub> in the body for long times (from 12 to 18 hrs) and that results particularly useful in those cases in which it is needed to supplement thyroid hormone in its most active form.

At page 6, please replace the paragraphs beginning at line 20 and ending at line 24 with the following paragraph:

On the contrary, the association of the invention avoids the above problems, because it has  $\frac{\text{unespectedly unexpectedly}}{\text{unexpectedly}}$  been found that, for example, after oral administration,  $T_3S$  provides  $T_3$  serum levels that increase in a gradual way and keep steady for long periods of time, thus preventing the formation of too much high peaks.